

Remarks

Claims 1 - 29 are pending. Favorable reconsideration is respectfully requested.

Claim 12 has been amended to clarify that component (A2) is in fact a diol. Withdrawal of the rejection under 35 U.S.C. § 112 ¶2 on this basis is solicited. Claims 25 and 28 contain the term “substantially” free of water. The Office has objected to the use of this term. The inventive compositions are moisture curable compositions. Thus, they must be prepared in the absence of any substantial amount of water, which would induce premature cure. It is impossible to remove all traces of water from organic compounds, and thus some minuscule amount of water will always remain, hence the use of “substantially free.” The claims are addressed to one skilled in the art, who recognizes that small amounts of water which do not interfere with the storage and subsequent curing of the compositions is tolerable. The term “substantially” has been approved of in numerous instances. *See, e.g. Verve LLC v. Crane Cams, Inc.*, 65 USPQ 2d 1051 (Fed. Cir. 2002). In the *Verve* case, the term “substantially constant wall thickness” had been held by the lower court to be indefinite under 35 U.S.C. § 112. The Federal Circuit reversed. As stated by the *Verve Court*:

Patent documents are written for persons familiar with the relevant field; the patentee is not required to include in the specification information readily understood by practitioners, lest every patent be required to be written as a comprehensive tutorial and treatise of the generalist, instead of a concise statement for persons in the field. Thus resolution of any ambiguity arising from the claims and specification may be aided by extrinsic evidence of usage and meaning of a term in the context of the invention. The question is not whether the word “substantially” has a fixed meaning as applied to “constant wall thickness,” but how the phrase would be understood by persons experienced in this field of mechanics, upon reading the patent documents.

Verve at 1053-54. The Court further stated:

Expressions such as “substantially” are used in patent documents when warranted by the nature of the invention, in order to accommodate the minor variations that may be appropriate to

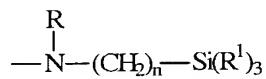
secure the invention. Such usage may well satisfy the charge to “particularly point out and distinctly claim” the invention, 35 U.S.C. § 112, and indeed may be necessary in order to provide the inventor with the benefit of his invention. In Andrew Corp. v. Gabriel Elecs. Inc., 847 F.2d 819, 821-22, 6 USPQ 2d 2010, 2013 (Fed. Cir. 1988) the court explained that usages such as “substantially equal” and “closely approximate” may serve to describe the invention with precision appropriate to the technology and without intruding on the prior art. The court again explained in Ecolab Inc. v. Envirochem, Inc., 264 F. 3d 1358, 1367, 60 USPQ 2d 1173, 1179 (Fed. Cir. 2001) that “like the term ‘about’, the term ‘substantially’ is a descriptive term commonly used in patent claims to ‘avoid a strict numerical boundary to the specified parameter,’ quoting Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217, 36 USPQ 2d 1225, 1229 (Fed. Cir. 1995).

It is well established that when the term “substantially” serves reasonably to describe the subject matter so that its scope would be understood by persons in the field of the invention, and to distinguish the claimed subject matter from the prior art, it is not indefinite.

Verve at 1054. Withdrawal of the rejection of claims 25 and 28 on this basis under 35 U.S.C. § 112 ¶2 is therefore respectfully requested.

Claims 12 - 22 and 24 - 28 have been rejected under 35 U.S.C. § 102(b) as anticipated by Müller et al. U.S. Patent 5,118,290 (“*Müller*”). Applicants respectfully traverse this rejection.

Müller discloses dental restoration molding compositions (“dental impression materials”) which contain alkoxy silyl-terminated polyurethane ureas, and which are cured by blending with copious amounts of water. The alkoxy silyl end groups have the formula



where R is hydrogen or a further $-Si(R^1)_3$ group, and at least one R^1 is C_{1-4} alkoxy, the remaining R^1 's being methyl or ethyl groups. While n values of 1 - 6 are cited, only n=3 is exemplified, as only "spacer" groups of 3 carbons and higher are believed to have been accessible to Müller at the time of his application (DE) in 1986. These alkoxy silane end groups are prepared by hydrosilylation of allylamine or higher ω -aminoalkenes with a hydridoalkoxysilane. Hydrosilylation of vinyl amine is not possible since vinyl amine, like vinyl alcohol, is not a stable species, and the corresponding methylene compound, having but one carbon, is obviously incapable of having a hydrosilylatable ethylenic double bond.

Müller's polyurethaneurea polymers are prepared by reacting a polyether diol with an aliphatic or cycloaliphatic diisocyanate and with an aminoalkylalkoxysilane. Freedom from residual isocyanate groups is not mentioned in the disclosure *per se*, but in the Examples, in the last step, when the ω -aminopropyltriethoxysilane is reacted with the isocyanate-terminated prepolymer of the first step, it is indicated that NCO groups can no longer be detected.

Müller also discloses the use of low molecular weight diols in conjunction with the polyether diol, but only in amounts from 0 parts (none) to 0.6 parts, preferably 0 to 0.2 parts per 1 part of polyether diol, a mol ratio of 1:0 to 1:0.6, preferably 1:0 to 1:02. See *Müller* at column 2, line 60 to column 3, line 4. The claims have been amended to recite that the ratio of polyether diol A1 to diol A2 is from 1:0.7 to 1:7 (expressed as the ratio of A2 to A1, 0.7:1 to 7:1), support in the specification being found on page 6, line 37 to page 7, line 2. Withdrawal of the rejection of the claims under 35 U.S.C. § 102(b) over *Müller* is therefore solicited. It is noted that claim 24 as presented contained the ratio of 1:0.7 to 1:3, also outside of the range disclosed by Müller.

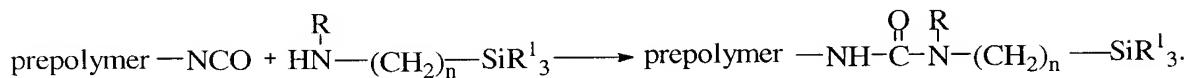
Nor are the claims obvious over Müller, as there would be no motivation to employ a larger amount of diol. Müller actually prefers no low molecular weight diol at all, and with good reason, as addition of low molecular weight diols into a polyurethane urea inserts so-called "hard segments" which, due to their termination with polar urethane groups

(or urea groups when low molecular weight diamines are employed) causes the viscosity of the prepolymer to rise, even sometimes to the point where solidification can occur, and the hard segments make the cured polymer much more rigid. In dental restoration work, as is well known, the dental impression material must be highly flexible and extensible in order to correctly produce a dental impression and be removable from the patients mouth without damage. Molar teeth have undercuts (being broader at the top than the base) which would prevent removal of the female mold from the teeth if the cured impression material is rigid. Thus, one skilled in the art would not be motivated to employ the claimed diol content, but would be motivated to use no diol at all, or a very minor amount, within *Müller's* preferred range.

With respect to claim 18, the use of these particular compounds to form the alkoxy silane end groups produces polymers which are highly reactive towards water. The reactivity is so high, as compared to products employing a propylene $[-(\text{CH}_2)_3-]$ group rather than the methylene $[-\text{CH}_2-]$ group of claim 18, that these products would polymerize immediately if blended with water as in Müller. Müller was obviously unaware of the surprising and unexpected reactivity of these compounds, which is so high that any attempt to mix with water to produce an impression material would fail, as the polymer would cure immediately and would be therefore unable to be applied to form a mold in the patient's mouth. Müller never tested such materials, for reasons explained earlier, and if he had, would have excluded them from his claims as they would be totally unsuited for his purpose.

New claims 29 - 31 have been added to more particularly point out and distinctly claim certain preferred aspects of Applicants' invention. In claim 29, the B^1 group of claim 18 has been limited to an -OH group. As a result of employing either a hydroxymethylalkoxysilane or isocyanatomethylalkoxysilane, the resulting end groups are completely different from those employed by Müller. The polymers prepared thereby are polyurethanes, in contrast to the polymers of Müller which must also contain urea groups due to his use of an aminoalkylalkoxysilane capping agent. The amino group reacts with an isocyanate group to form a urea group, not a urethane group. Claim 30 is similar to claim 14,

but eliminates the urea groups which are possible to be formed from *Müller's* aminoalkylalkoxysilane, which are limited by his capping reaction:



Claim 31 pertains to certain preferred water scavengers having the formula $\text{B}^2(\text{CH}_2)-\text{SiR}^1_a(\text{OR}^2)_{3-a}$, support for which may be found on page 17 of the application. Müller describes none of these, nor would he, as these compounds preferentially react with water to scavenge water from the system, whereas Müller adds copious amounts of water for curing. All the compounds listed have far higher reactivity than the tetralkoxysilane crosslinkers employed by Müller, which are also used for a different purpose (crosslinking, not water scavenging).

New claim 32 pertains to compositions including an adhesion promoter which contains an amino group or epoxy group. Müller would not wish to include an adhesion promoter, which would render his compositions unremovable from the patient's teeth.

Claims 12 - 28 have been rejected under 35 U.S.C. § 102(b) as anticipated by Majolo U.S. 6,790,903 ("Majolo"). Applicants respectfully traverse this rejection. The claimed compounds are terminated by $\text{SiR}^1_a(\text{OR}^2)_{3-a}$ groups where R^2 is an alkyl group or ω -oxyalkyl group. *Majolo* is directed to aqueous dispersions containing silanol-terminated polyurethanes, i.e. polyurethanes having $-\text{A}-\text{Si}(\text{Z}_n)(\text{OH})_{3-n}$ groups, where n is 0, 1, or 2. These polymers must therefore each contain at least one silanol ($\equiv\text{Si-OH}$) group. Applicants' polymers do not contain these groups, as can be seen from their formula. Withdrawal of the rejection of claims 12 - 28 on this basis is respectfully solicited.

In addition, Applicants require a distinct polymer diol/low molecular weight diol ratio. This ratio is important in obtaining the desired properties. The only disclosure of any amount of low molecular weight chain extender by *Majolo* is found in column 3, lines 24 - 26, where it is stated to be possible to use "up to 20% by weight" of chain extender, based on the weight of the polyurethane. Since this ratio is based on the weight of the polyurethane and

not the polyether, the range with respect to the latter is virtually unlimited, for example from 0 parts chain extender to 1 part polyether to >> 999 parts chain extender to one part polyether, as long as the total amount of chain extender is not more than 20% of the total weight of the polyurethane. No examples employ any chain extender.

Such a broad disclosure is not novelty defeating. This situation has been recently addressed again by the Courts in *Atofina v. Great Lakes Chemical Corp.*, 78 USPQ 2d 14 17 (Fed. Cir. 2006). In *Atofina*, gas phase fluorination of methylene chloride with HF was claimed. The claim at issue was a process claim which contained three distinct ranges: a temperature range of 330°C to 450°C; an oxygen to methylene chloride molar ratio of 0.1 to 5.0 percent; and a contact time of 0.01 to 10 seconds. With respect to the latter, the alleged anticipatory reference was silent, and the Federal Circuit had no hesitancy in indicating that there was no anticipation of that contact time range either literally or by inherency. The other two ranges were carefully reviewed by the Court and compared with the ranges in the reference. The Table below might be helpful in understanding the Court's holding.

Patent Claimed Range	JP Reference Disclosure		
	broadest	preferred	example
330 - 450°C	100 - 500°C	150 - 350°C	none within 330 - 450°
0.1 - 5.0 mol ratio O ₂ /CH ₂ Cl ₂	0.001 - 1	none	none within 0.1 - 5.0

Note that the claimed temperature range is completely within the references broad range of 100 - 500°C, and even overlaps the preferred range. The Court concluded that there was no anticipation, since neither endpoint of the claimed range was disclosed by the reference, and there was no actual example within the claimed range.¹ That is the case here.

The same was true for the O₂/CH₂Cl₂ mol ratio. The claimed range was not

¹ The Court acknowledges that an actual example (species) within the claimed range or an identical endpoint (also a species), would have anticipated.

disclosed. While there was an overlap between the claimed range and the range disclosed by the reference, there were no identical endpoints, nor was any actual example within the claimed range. Thus, there was no anticipation.

For all these reasons, withdrawal of the rejections of claims 12 - 28 is solicited.

With respect to the dependent claims, the differences between the claimed invention and that disclosed by *Majolo* is even more striking. The present compositions are room temperature curable by exposure to atmospheric moisture. *Majolo's* compositions are prepared as an aqueous dispersion. If *Majolo's* polymers are in any way similar to Applicants, then they would not be curable, since they are prepared in aqueous dispersion with an enormous stoichiometric excess of water. If they were water-curable, they would cure as the dispersion is made, and would be cured, not curable.

With respect to claim 18 in particular, the Applicants' claimed compounds react so fast that their reaction would be complete or nearly complete even before the finished dispersion could be made. It would be expected that considerable amounts of coagulum would be formed (expressly desired to be avoided by *Majolo*, as disclosed in column 2, lines 14 - 16), or even complete solidification or gelling would occur. With respect to claims 25 and 28, *Majolo* prepares aqueous dispersions, the entire purpose of his invention, which clearly are not substantially free of water.

Claim 23 has been rejected under 35 U.S.C. § 103(a) over *Müller* in view of *Majolo*. Applicants find no motivation to combine these references. In the case of *In re Anita Dembiczak and Benson Zinbarg*, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999), the CAFC has indicated that the requirement for showing the teaching or motivation to combine references is "rigorous." *Dembiczak* at 1617. Moreover, this showing, which is rigorously required, must be "clear and particular." *Dembiczak* at 1617. See also, *C.R. Bard v. M3 Sys., Inc.*, 48 U.S.P.Q.2d 1225, 1232 (Fed. Cir. 1998). It is well established that merely because references can be combined, the mere suitability for logical combination does not provide motivation for

the combination. See, *Berghauser v. Dann, Comr. Pats.*, 204 U.S.P.Q. 398 (DCDC 1979); *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 221 U.S.P.Q. 929 (Fed. Cir. 1984). Moreover, mere conclusory statements supporting the proposed combination, standing alone are not "evidence". *McElmurry v. Arkansas Power & Light Co.*, 27 U.S.P.Q.2d 1129, 1131 (Fed. Cir. 1993). See also, *In re Lee*, 61 U.S.P.Q. 2d 1430 (Fed. Cir. 2002).

Majolo is directed to aqueous dispersions of silanol-terminated polyurethanes, which set into coatings by evaporation of water and coalescence of the polymer particles, which have a low film formation temperature. See, e.g. column 18, lines 42 - 43, and column 17, lines 8 - 29. Such materials are clearly not suited for use in *Müller*'s invention, since due to the inherent moisture in the mouth, no elastomer would be formed at all, or if formed, would take hours, not minutes, as required for dental impression materials due to the slow evaporation of water, if indeed evaporation occurs at all. The very great differences between the basic characteristics of the references motivates against combination.

Furthermore, the aminoalkylalkoxysilanes of *Müller* are expressly chosen so that urea groups may be incorporated into his polyurethaneurea polymers. Other isocyanate-reactive groups such as hydroxyl, thiol, etc., cannot do this, and many of the groups suggested by *Majolo* are incapable of reaction with *Müller*'s isocyanate-terminated prepolymers under any reasonable conditions. Examples include isocyanate-functional, halide group, acid halide group, etc. The "Y" group of *Majolo* is a hydroxyl-reactive group (col. 9, lines 15 - 16) whereas in *Müller*, the "Y" group must be an isocyanate-reactive group. These teachings are diametrically opposed and cannot be combined. Applicants have also previously discussed further unobvious benefits of the claimed invention with regard to the individual references. These also apply to the combination of references, were such a combination proper. Withdrawal of the rejection of claim 23 under 35 U.S.C. § 103(a) is solicited.

Applicants submit that the claims are now in condition for Allowance, and respectfully request a Notice to that effect. If the Examiner believes that further discussion will advance the prosecution of the Application, the Examiner is highly encouraged to telephone Applicants' attorney at the number given below.

Please charge any fees or credit any overpayments as a result of the filing of this paper to our Deposit Account No. 02-3978.

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